

"Express Mail" Mailing Label No. EL 847 787 701 US  
Date of Deposit AUGUST 3, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service  
"Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated  
above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan LaMont  
Typed or Printed Name of Person Mailing Paper or Fee

Susan LaMont  
Signature of Person Mailing Paper or Fee

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

O'CONNOR et al.

Serial No.: §365(c) of PCT/GB00/00349      Group Art Unit: Unassigned

Filing Date: Even Date Herewith      Examiner: Unassigned

Title:      HYDROGEL PARTICLE FORMULATIONS

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This Amendment accompanies the §365(c) filing of  
PCT/GB00/00349. Accompanying this Amendment are marked-up claim and  
specification pages, showing the amendments made herein.

Entry of these amendments is respectfully requested.

Amendment

In the Specification:

At page 1, before line 1, please insert:

--Cross-Reference to Related Application

This application is a §365(c) filing of International Patent Application No. PCT/GB00/00349, filed February 3, 2000, designating the United States, from which priority is claimed pursuant to 35 U.S.C. §120 and also claims priority under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/118,334, filed February 3, 1999, which applications are incorporated herein by reference in their entireties--

In the Claims:

Please amend the claims as follows:

3. (Amended) Use according to claim 1, wherein the envelope density of the particles is from 0.8 to 1.5 g/cm<sup>3</sup>.

4. (Amended) Use according to claim 1, wherein the pharmacologically active agent is a gene construct.

6. (Amended) Use according to claim 1, wherein the hydrogel is agarose or dextran.

15. (Amended) The method of claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.

16. (Amended) The method of claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.

17. (Amended) The method of claim 10, wherein the hydrogel particles are selected from the group consisting of agarose, dextran, polyethylene glycol and polybutyleneterephthalate particles.

18. (Amended) The method of claim 10, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

19. (Amended) The method of claim 10, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

20. (Amended) The method of claim 10, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

23. (Amended) The composition of claim 21, wherein the hydrogel is agarose.

24. (Amended) The composition of claim 21, wherein the active agent is a peptide.

25. (Amended) The composition of claim 21 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

26. (Amended) A unit dosage form of the composition of claim 21.

27. (Amended) An article of manufacture for the transdermal or transmucosal delivery of a pharmacologically-active agent to a subject, which article comprises a pharmaceutical composition of claim 21 in a container containing a unit dose of active agent.

29. (Amended) The article of manufacture of claim 27, wherein the active agent is a peptide or protein.

30. (Amended) The article of manufacture of claim 27 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

31. (Amended) A method for delivering a drug to a subject in need thereof, which method comprises preparing a pharmaceutical composition of claim 24, accelerating said particles to a high velocity, and delivering said accelerated particles into a target skin or mucosal site.

33. (Amended) The method of claim 31, wherein the active agent is a peptide.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned **“Version with markings to show changes made.”**

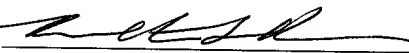
#### REMARKS

Applicants, by way of this Preliminary Amendment, have eliminated multiple dependencies from the claims. Moreover, the specification has been amended to insert a claim for priority.

Accordingly no new matter has been added by way of the above  
amendments, and the entry thereof is respectfully requested.

Respectfully submitted,

Date: 8/3/01

By:   
Roberta L. Robins  
Registration No. 33,208

ROBINS & PASTERNAK LLP  
90 Middlefield Road, Suite 200  
Menlo Park, CA 94025  
Telephone: (650) 325-7812  
Fax: (650) 325-7823

**Version with markings to show changes made**

The claims have been amended as follows:

3. (Amended) Use according to claim 1 [or 2], wherein the envelope density of the particles is from 0.8 to 1.5 g/cm<sup>3</sup>.
4. (Amended) Use according to [any one of the preceding claims] claim 1, wherein the pharmacologically active agent is a gene construct.
6. (Amended) Use according to [any one of the preceding claims] claim 1, wherein the hydrogel is agarose or dextran.
15. (Amended) The method of [any one of claims 10 to 14] claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a dry state.
16. (Amended) The method of [any one of claims 10 to 14] claim 10, wherein the hydrogel particles in step (b) are contacted with the aqueous composition while in a wet, pre-hydrated state.
17. (Amended) The method of [any one of claims 10 to 16] claim 10, wherein the hydrogel particles are selected from the group consisting of agarose, dextran, polyethylene glycol and polybutyleneterephthalate particles.

18. (Amended) he method of [any one of claims 10 to 17] claim 10, wherein the active agent is present in the powdered pharmaceutical composition in an amount ranging from about 0.1 to 85 wt% of the composition.

19. (Amended) The method of [any one of claims 10 to 18] claim 10, wherein the powdered pharmaceutical composition is formed using a freeze-drying step.

20. (Amended) The method of [any one of claims 10 to 18] claim 10, wherein the powdered pharmaceutical composition is formed using a spray-drying step.

23. (Amended) The composition of claim 21 [or 22], wherein the hydrogel is agarose.

24. (Amended) The composition of [any one of claims 21 to 23] claim 21, wherein the active agent is a peptide.

25. (Amended) The composition of [any one of claims 21 to 24] claim 21 in combination with written labeling instructions for administration of the particles by transdermal or transmucosal, high-velocity, powder injection.

26. (Amended) A unit dosage form of the composition of [any one of claims 21 to 24] claim 21.

27. (Amended) An article of manufacture for the transdermal or transmucosal delivery of a pharmacologically-active agent to a subject, which



article comprises a pharmaceutical composition of [any one of claims 21 to 24]  
claim 21 in a container containing a unit dose of active agent.

29. (Amended) The article of manufacture of claim 27 [or 28], wherein  
the active agent is a peptide or protein.

30. (Amended) The article of manufacture of [any one of claims 27 to 29]  
claim 27 in combination with written labeling instructions for administration of  
the particles by transdermal or transmucosal, high-velocity, powder injection.

31. (Amended) A method for delivering a drug to a subject in need  
thereof, which method comprises preparing a pharmaceutical composition of [any  
one of claims 21 to 24] claim 24, accelerating said particles to a high velocity, and  
delivering said accelerated particles into a target skin or mucosal site.

33. (Amended) The [process] method of claim 31 [or 32], wherein the  
active agent is a peptide.